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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/715,787 | 11/18/2003 | Alexander Andrianov | 533860-101 | 4559 |

7590 01/03/2006

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| EXAMINER |
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LE, EMILY M

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| ART UNIT | PAPER NUMBER |
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1648

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,787

Applicant(s)

ANDRIANOV ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-11 are pending. Claims 8-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/24/2005. Claims 1-7 are under examination.

Specification

2. Previously stated objection to the drawing under 37 CFR 1.83(a) is withdrawn in view of Applicant's 09/28/2005 submission of a replacement sheet for Figure 1.

Claim Objections

3. Previously stated objection to claims 1-7 is withdrawn in view of Applicant's 09/28/2005 submission. It is readily apparent that the recitation "salt thereof" is directed at the organic amine.

Claim Rejections - 35 USC § 112

4. Previously stated indefinite rejection to claim 2 is withdrawn in view of Applicant's 09/28/2005 submission.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrianov et al. in view of Pelta et al.

In response to the rejection, Applicant submits that Andrianov teaches the production of coacervate microdroplets from aqueous solutions of polyphosphazene upon the addition of sodium chloride as coacervating agent, and stabilization of the microdroplets with calcium chloride to yield polyphosphazene microspheres. Applicant contends that Andrianov does not teach the production of polyphosphazene microspheres, rather Andrianov teaches the production of polyphosphazene microdroplets.

Applicant's submission has been considered, however, it is not found persuasive. Andrianov et al. does teach the production of polyphosphazene microspheres, see the title and abstract of Andrianov et al., and Applicant's 09/28/2005 submission, which states that Andrianov et al. teaches a yield of "polyphosphazene microspheres". In the instant, it is recognized that the method of Andrianov et al. teaches entails more ingredients and other active method steps than those recited in the claims, however, Andrianov continues to teach the claimed invention because the claimed invention encompasses the teaching provided by Andrianov. The claims are not limited solely to the ingredients and method steps recited in the claims. The claims are open to the inclusion of other ingredients and method steps. Thus, Applicant's submission is not sufficient to overcome the rejection.

Additionally, Applicant submits that Andrianov et al. does not mention the use of organic amines, and teaches away from the use of organic solvents, as exemplified by the last paragraph, first column, page 109 of Andrianov et al.

Applicant's submission has been considered, however, it is not found persuasive. It appears that Applicant has taken the teaching of Andrianov et al. outside of its intended context. In the instant, Andrianov et al. notes the attractiveness of poly[di(carboxylatophenoxy)phosphazene] as a candidate material for microencapsulation. Andrianov et al. clearly does not teach away from the use of organic solvents for Andrianov et al. does use organic solvents with poly[di(carboxylatophenoxy)phosphazene]. The organic solvent used by Andrianov et al. is sodium chloride.

Additionally, Applicant is correct to note that Andrianov et al. does not mention the use of organic amines. Had Andrianov et al. mention or teach the use of organic amines, then the Office would not have relied on the teaching of Pelta et al., in conjunction with Andrianov et al., for the instant rejection.

In the instant, it is agreed that Andrianov et al. does not teach the use of organic amines, including spermine. However, the deficiency noted in Andrianov et al. is fully compensated by Pelta et al. Pelta et al. teaches the use of organic amines. The organic amines Pelta et al. teaches include spermine. In the instant, Pelta et al. recognizes the use of spermine as a coacervating agent. The coacervating agent used by Pelta et al. is different from that of Andrianov et al. Andrianov et al. teaches the use of sodium chloride as a coacervating agent. In the instant, both references teach of coacervating

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agents. Thus, at the time the invention was made, both spermine and sodium chloride are well recognized in the art as coacervating agents. Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use one art recognized coacervating agent, spermine, for another coacervating agent, sodium chloride. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because spermine is an art recognized functional equivalent for sodium chloride as a coacervating agent. Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

In addition to the submissions addressed above, Applicant submits that Pelta et al. makes no mention of polyphosphazenes or microspheres.

This submission has been considered, however, it is not found persuasive. the instant rejection is made on the combined teachings of Andrianov et al. and Pelta et al., not just solely Pelta et al. or Andrianov et al. Thus, submission(s) directed at disqualifying each reference, separately, have no merits.

Additionally, it is recognized that Applicant submits that Pelta suggests a lack of interchangeability of sodium chloride and organic amines as coacervating agents, insofar as their co-presence in solution prevents rather than expedites precipitation. The instant submission has been considered, however, it is not found persuasive. Pelta et al. clear sets forth that the influence of sodium chloride and precipitates. Pelta et al. teaches that an increase in sodium chloride concentration leads to an almost complete

precipitation, and further increases in sodium chloride concentration leads to the resolubilization of the precipitates. [first full paragraph, Results section, page 5657]

This teaching is not a teaching of lack of interchangeability of sodium chloride and organic amines as coacervating agents, as suggested by Applicant.

Conclusion

7. No claim is allowed.

8. Any **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


E. Le


Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
Art Unit 1648